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THE REPORT OF THE PROPERTY OF THE PERSON OF

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- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR. HU, ID, IL, IN, IS, JP, KE, KG, KR, KZ, LC, LK, LR. LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO. RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
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Published:

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: AQUEOUS NASAL FORMULATION

(57) Abstract: The present invention provides an aqueous nasal formulation comprising beclomethasone dipropionate anhydrate for use in the treatment of respiratory disorders.

PATENT COOPERATION TREATMY

From the

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY .

To:

SUZUYE, Takehiko et al. SUZUYE & SUZUYE 7-2 Kasumigaseki 3-chome,

Chiyoda-ku, Tokyo 100-0013

JAPON.

7 JUN 4 291 F

SUM MER GUMUYE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing

(day/month/year)

01.06.2001

Applicant's or agent's file reference

International application No.

PCT/JP00/05200

00S0828P

International filing date (day/month/year)

03/08/2000

Priority date (day/month/year)

IMPORTANT NOTIFICATION

07/08/1999

Applicant

GLAXO WELLCOME KABUSHIKI KAISHA et al.

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

European Patent Office D-80298 Munich

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Fax: +49 89 2399 • 4465

Authorized officer

Longo, E

Tel.+49 69 2399-8141





PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| 00S0828P | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|--|---|
| International application No. | international filing date (day/mont | Priority date (day/month/year) |
| PCT/JP00/05200 | 03/08/2000 | 07/08/1999 |
| International Patent Classification (IPC A61K9/08 | c) or national classification and IPC | |
| GLAXO WELLCOME KABUSH | HIKI KAISHA et al. | |
| This international preliminary and is transmitted to the appl | | d by this International Prellminary Examining Authority |
| 2. This REPORT consists of a to | otal of 5 sheets, including this cover s | heet. |
| been amended and are to (see Rule 70.16 and Sec | he basis for this report and/or sheets tion 607 of the Administrative Instruct | ne description, claims and/or drawings which have containing rectifications made before this Authority ions under the PCT). |
| These annexes consist of a to | otal of sheets. | • |
| | | |
| [: | ns relating to the following items: | |
| I ⊠ Basis of the repo | rt | |
| II 🗆 Priority | | |
| III 🛭 Non-establishme | nt of opinion with regard to novelty, in | ventive step and industrial applicability |
| IV 🗀 Lack of unity of le | nvention | |
| | nent under Article 35(2) with regard to lanations suporting such statement | novelty, inventive step or industrial applicability; |
| VI 🔲 Certain docume | nts cited : | |
| ł | n the international application | |
| VIII ☐ Certain observati | lons on the international application | |
| Date of submission of the demand | Oate of | completion of this report |
| 18/01/2001 | 01.06.2 | 2001 |
| Name and mailing address of the inter preliminary examining authority: | national Authori | zed officer |
| European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: | · · · · · · · · · · · · · · · · · · · | han a same a |
| Fax: +49 89 2399 - 4465 | Telepho | one No. +49 89 2399 8654 |

International application No. PCT/JP00/05200

| Į, | Bas | is of the report | |
|--------------|---------|---|---|
| 1. | the and | receiving Office in I | nents of the international application (Replacement sheets which have been furnished to response to an invitation under Article 14 are referred to in this report as foriginally filed this report since they do not contain amendments (Rules 70.16 and 70.17)): |
| , . . | 1-12 | <u>2</u> | as originally filed |
| | Clai | ms, No.: | |
| | 1-9 | | as originally filed . |
| | Dra | wings, sheets: | |
| | 1/5- | 5/5 | as originally filed |
| | | | |
| 2. | With | n regard to the language in which the i | uage, all the elements marked above were available or furnished to this Authority in the international application was filed, unless otherwise indicated under this item. |
| | The | se elements were a | available or furnished to this Authority in the following language: , which is: |
| | | the language of a | translation furnished for the purposes of the international search (under Rule 23.1(b)). |
| | | the language of pu | ublication of the international application (under Rule 48.3(b)). |
| | | the language of a 55.2 and/or 55.3). | translation fumished for the purposes of intemational preliminary examination (under Rule |
| 3. | With | n regard to any nuc rnational preliminar | eleotide and/or amino acid sequence disclosed in the international application, the yexamination was carried out on the basis of the sequence listing: |
| | | contained in the in | ternational application in written form. |
| · | ۵ | filed together with | the international application in computer readable form. |
| -5 | | furnished subsequ | rently to this Authority in written form. |
| | | • | rently to this Authority in computer readable form. |
| | | The statement that the international a | it the subsequently furnished written sequence listing does not go beyond the disclosure in pplication as filed has been furnished. |
| | | The statement that listing has been full | t the information recorded in computer readable form is identical to the written sequence rnished. |
| 4. | The | amendments have | e resulted in the cancellation of: |
| | | the description, | pages: |
| | | the claims, | Nos.: |

International application No. PCT/JP00/05200

| □ the drawfings, sheets: □ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(ci)): (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.) 6. Additional observations, if necessary: III. Non-establishment of opinion with regard to novelty, inventive step and Industrial applicability 1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of: □ the entire international application. □ claims Nos. 8, as far as industrial applicability is concerned. because: □ the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination (specify): see separate sheet □ the description, claims or drawlings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): □ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. □ no international search report has been established for the said claims Nos. 2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard. □ the written form has not been furnished or does not comply with the standard. □ the computer readable form has not been furnished or does not comply with the standard. V. Reasoned statement under | | | | | | | | | | | | |
|--|-------------|------|--|-----------------------------------|----------------------------|----------------------|--------------------------------------|------------------------|-------------------------------|--------------------------|---------------------------------|-------|
| considered to go beyond the disclosure as filed (Hule 70.2(c)): (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.) 6. Additional observations, if necessary: III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability 1. The questions whether the claimed invendon appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of: the entire international application. claims Nos. 8, as far as industrial applicability is concerned. because: the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination (specify): see separate sheet the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. no international search report has been established for the said claims Nos. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement Statement | | • | | | | | | | | | | |
| 6. Additional observations, if necessary: 11. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability 1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of: the entire international application. claims Nos. 8, as far as industrial applicability is concerned. because: the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination (specify): see separate sheet the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. no international search report has been established for the said claims Nos. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. The second statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement Statement | 5. | | considered to go bey | rond the disclos | sure as | tiled (I | Hule 70.2(0 | c)): | | | | |
| III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability 1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of: the entire international application. claims Nos. 8, as far as industrial applicability is concerned. because: the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination (specify): the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. no international search report has been established for the said claims Nos. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. The sasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement S | | | (Any replacement sh report.) | eet containing | such a | mendn | nents must | be referre | ed to under | item 1 and | d annexed to | this |
| The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of: | 6. | Add | itlonal observations, i | f necessary: | | | | | | | | |
| The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of: | Ш. | Nor | n-establishment of o | plnion with re | gard t | o nove | lty, inventi | ive step a | and industri | al applic | ability | |
| because: the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination (specify): see separate sheet | 1. | The | questions whether th | e claimed inve | ntion a | ppears | to be nove | el, to invol | lve an inven | tive step (| to be non- | |
| because: ☑ the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination (specify): see separate sheet ☐ the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. ☐ no international search report has been established for the said claims Nos 2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: ☐ the written form has not been furnished or does not comply with the standard. ☐ the computer readable form has not been furnished or does not comply with the standard. ☐ the computer readable form has not been furnished or does not comply with the standard. ☐ the written form has not been furnished or does not comply with the standard. ☐ the computer readable form has not been furnished or novelty, inventive step or industrial applicability citations and explanations supporting such statement | : | | the entire internation | al application. | | | | | | | | |
| the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination (specify): see separate sheet the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. no international search report has been established for the said claims Nos. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. W. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement | | × | claims Nos. 8, as far | as industrial a | pplical | oility is | concerned. | | | | | |
| not require an international preliminary examination (specify): see separate sheet the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify): the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. no international search report has been established for the said claims Nos. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. W. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement | be | caus | | | | | | | | | | |
| that no meaningful opinion could be formed (specify): the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. no international search report has been established for the said claims Nos A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement | | × | not require an intern | ational prelimin | r the sa nary ex | aid clair aminat | ms Nos. 8 i ion (<i>specif</i>) | relate to th | ne following | subject m | atter which d | loes |
| could be formed. no international search report has been established for the said claims Nos A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. W. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement Statement | | | the description, clair that no meaningful c | ns or drawings pinion could be | (<i>indica</i> e forme | ate pari ed (spe | ticular elem cify): | nents belo | w) or said c | aims Nos | are so uncl | ear |
| could be formed. no international search report has been established for the said claims Nos A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. W. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement Statement | <u>a</u> f. | | er far | | | | | | | | | |
| 2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement Statement | - * | | | laims Nos. are | so ina | idequat | tely suppor | ted by the | description | that no π | teaningful opt | IUIOL |
| and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: the written form has not been furnished or does not comply with the standard. the computer readable form has not been furnished or does not comply with the standard. V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement Statement | | | no international sea | rch report has I | been e | stablish | ned for the | said clain | ns Nos | | | |
| the computer readable form has not been furnished or does not comply with the standard. V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement 1. Statement | 2. | and | Vor amino acid seque | al preliminary ence listing to c | examin omply | ation ca with the | annot be ca e standard | arried out provided | due to the fa for in Annex | ailure of th C of the | ie nucleotide Administrative | Э |
| the computer readable form has not been furnished or does not comply with the standard. V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability citations and explanations supporting such statement 1. Statement | | | the written form has | not been furnis | shed o | r does | not comply | with the | standard. | | | |
| citations and explanations supporting such statement 1. Statement | | | | | | | | | | standard. | | |
| Novelty (N) Yes: Claims 1-9 | ÷- | cita | ations and explanati | nder Article 35 ons supportin | 5(2) wi Iy suc | th rega h state | ard to nove ment | elty, inve | ntive step a | r industr | ial applicabil | lity; |
| | | No | veity (N) | Yes: C | laims | 1-9 | | | | | | |

International application No. PCT/JP00/05200

No:

Claims

Inventive step (IS)

Yes:

Claims 1-9

No:

Claims

Industrial applicability (IA)

Yes:

Claims 1-7,9

No:

Claims

2. Citations and explanations see separate sheet

INTERNATIONAL PRELIMINARY International application No. PCT/JP00/05200 EXAMINATION REPORT - SEPARATE SHEET

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and Industrial applicability

Claim 8 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

For the assessment of the present claim 8 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment like claimed in claim 7.

Novelty(Art.33(2) PCT):

A pharmaceutical formulation which comprises an aqueous solution of carboxymethylcellulose sodium, glycerol, porpylene glycol and polyoxyethylene (20) sorbitan monooleate, containing suspended therein particulate microcrystalline cellulose and beclomethasone dipropionate anhydrate and dextrose, phenylethyl alcohol, benzalkonium chloride, disodiumhydrogenorthophosphate and citric acid is not disclosed in the prior art. Subject matter of claims 1-9 is therefore regarded to be novel over the prior art.

Inventive Step (Art. 33(3) PCT):

Closest prior art is regarded to be EP-A-780127. Difference to the present application: The prior art composition lacks several of the ingredients. Problem was to find an improved preparation. This problem was solved by the claimed combination of ingredients. This solution is not regarded as being obvious for the skilled person, as not specifically envisaged or recommended in the art. Thus subject matter of claims 1-9 is regarded to involve an inventive step.





(PCT Article 36 and Rule 70)

| Applicant's | or age | ent's file reference | 1 | |
|---|--------------------|---|---|--|
| 0080828 | | | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| Internation | al appli | cation No. | International filing date (day/monti | th/year) Priority date (day/month/year) |
| PCT/JPC | 0/052 | 200 | 03/08/2000 | 07/08/1999 |
| A61K9/0 Applicant GLAXO 1. This i and is 2. This I | WELL nternas trans | COME KABUSHIKI Kational preliminary examinited to the applicant at RT consists of a total of port is also accompanies | ination report has been prepared according to Article 36. 5 sheets, including this cover s | sheet. The description, claims and/or drawings which have containing rectifications made before this Authority |
| | | exes consist of a total of | of the Administrative Instructions sheets. | ions under the PCT). |
| 3. This r | eport (| contains indications rela | ting to the following items: | |
| 1 | _ | Basis of the report | | |
| H | | Priority | | , |
| Ш | | | | ventive step and industrial applicability |
| IV | | Lack of unity of invention | | |
| V | × | Reasoned statement ur citations and explanatio | nder Article 35(2) with regard to i ons suporting such statement | novelty, inventive step or industrial applicability; |
| VI | | Certain documents cite | ed | |
| VII | | Certain defects in the in | ternational application | |
| VIII | | Certain observations on | the international application | |
| Date of sub | mission | of the demand | Date of c | completion of this report |
| 18/01/200 |)1 | | 01.06.20 | 001 |
| Name and n preliminary | examin | address of the international ing authority: | Authorize | red officer |
|) | D-802 | ean Patent Office 98 Munich 49 89 2399 - 0 Tx: 523656 | epmu d Uhl, M | STATE OF THE PARTY |
| | Fax: + | 49 89 2399 - 4465 | Tolophor | no No. 140 90 2200 9654 |

International application No. PCT/JP00/05200

| i. | Ba | asis fth r port | |
|----|-------------|---|---|
| 1 | the an | e receiving Office in | ments of the international application (Replacement sheets which have been furnished to response to an invitation under Article 14 are referred to in this report as "originally filed" to this report since they do not contain amendments (Rules 70.16 and 70.17)): |
| | 1- | 12 | as originally filed |
| | Cla | aims, No.: | |
| | 1-9 | e | as originally filed |
| | Dr | awings, sheets: | |
| | 1/5 | 5-5/5 | as originally filed |
| | | | |
| 2. | Wit lan | th regard to the lang guage in which the | guage, all the elements marked above were available or furnished to this Authority in the international application was filed, unless otherwise indicated under this item. |
| | The | ese elements were a | available or furnished to this Authority in the following language: , which is: |
| | | the language of a | translation furnished for the purposes of the international search (under Rule 23.1(b)). |
| | | | ublication of the international application (under Rule 48.3(b)). |
| | | the language of a 55.2 and/or 55.3). | translation furnished for the purposes of international preliminary examination (under Rule |
| 3. | Wit inte | h regard to any nuc ernational preliminar | leotide and/or amino acid sequence disclosed in the international application, the y examination was carried out on the basis of the sequence listing: |
| | | contained in the in | ternational application in written form. |
| | | filed together with | the international application in computer readable form. |
| | | furnished subsequ | ently to this Authority in written form. |
| | | furnished subsequ | ently to this Authority in computer readable form. |
| | | The statement that the international ap | the subsequently furnished written sequence listing does not go beyond the disclosure in oplication as filed has been furnished. |
| | | The statement that listing has been fur | the information recorded in computer readable form is identical to the written sequence rnished. |
| 4. | The | amendments have | resulted in the cancellation of: |
| | | the description, | pages: |

Nos.:

☐ the claims,

International application No. PCT/JP00/05200

| | | the drawings, | sheets: | | | | | | | | |
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| 5. | | This report has been considered to go bey | | | | | | nad not bee | en made, | since the | ey have been |
| | | (Any replacement sh report.) | eet contair | ing such | amend | ments mu | st be refe | erred to und | der item | 1 and anr | nexed to this |
| 6. | Add | litional observations, i | f necessary | / : | | | | | | | |
| 111. | Nor | n-establishment of o | pinion with | regard t | o nove | elty, inver | ntive step | o and indu | ıstrial ap | plicabilit | у |
| 1. | | questions whether th | | | | | | | ventive s | tep (to be | non- |
| | | the entire internation | al application | on. | | | | | | | |
| | × | claims Nos. 8, as far | as industri | al applica | bility is | concerne | d. | | | | |
| be | caus | se: | | | | | | | | | |
| | | the said international not require an international see separate sheet | | | | | | the follow | ing subje | ct matter | which does |
| | | the description, claim that no meaningful o | | | - | | ments be | <i>low</i>) or said | d claims | Nos. are | so unclear |
| | | the claims, or said cl could be formed. | aims Nos. | are so ina | adequa | tely suppo | orted by the | he descript | tion that r | no meanir | ngful opinion |
| | | no international sear | ch report h | as been e | stablisl | hed for the | e said cla | ims Nos | | | |
| 2. | and | eaningful internationa /or amino acid sequer ructions: | | | | | | | | | |
| | | the written form has | not been fu | rnished o | r does | not compl | y with the | e standard. | | | |
| | | the computer readab | le form has | not beer | furnisl | hed or doe | es not cor | mply with t | he standa | ard. | |
| | cita | soned statement un tions and explanatio | | | _ | | elty, inv | entive ste _l | p or indu | strial ap | plicability; |
| 1. | Stat | ement | | | | | | | | | |
| | Nov | elty (N) | Yes: | Claims | 1-9 | | | | | | |

International application No. PCT/JP00/05200

No:

Claims

Inventive step (IS)

Yes:

Claims 1-9

No:

Claims

Yes:

Claims 1-7,9

No:

Claims

2. Citations and explanations see separate sheet

Industrial applicability (IA)

EXAMINATION REPORT - SEPARATE SHEET

R It m III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 8 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Relatement under Article 35(2) with regard to novelty. inventive step or industrial applicability; citations and explanations supporting such statement

For the assessment of the present claim 8 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment like claimed in claim 7.

Novelty(Art.33(2) PCT):

A pharmaceutical formulation which comprises an aqueous solution of carboxymethylcellulose sodium, glycerol, porpylene glycol and polyoxyethylene (20) sorbitan monooleate, containing suspended therein particulate microcrystalline cellulose and beclomethasone dipropionate anhydrate and dextrose, phenylethyl alcohol, benzalkonium chloride, disodiumhydrogenorthophosphate and citric acid is not disclosed in the prior art. Subject matter of claims 1-9 is therefore regarded to be novel over the prior art.

Inventive Step (Art. 33(3) PCT):

Closest prior art is regarded to be EP-A-780127. Difference to the present application: The prior art composition lacks several of the ingredients. Problem was to find an improved preparation. This problem was solved by the claimed combination of ingredients. This solution is not regarded as being obvious for the skilled person, as not specifically envisaged or recommended in the art. Thus subject matter of claims 1-9 is regarded to involve an inventive step.

Intern. ial Application No PCT/JP 00/05200

| A. CLAS | SIFICATION OF SUBJECT MATTER | | 101701 0 | 0/05200 |
|-------------------------|--|---|--|-------------------------------------|
| IPC 7 | A61K9/08 A61K31/573 A61P3 | 7/08 | | |
| | to International Patent Classification (IPC) or to both national class | ssification and IPC | | |
| | S SEARCHED | | | |
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| | ation searched other than minimum documentation to the extent t | | | |
| EPO-In | data base consulted during the international search (name of data nternal, WPI Data, PAJ, CHEM ABS Da | a base and, where practical, s | earch terms used | 1) |
| | | | | |
| C. DOCUM | ENTS CONSIDERED TO BE RELEVANT | | | |
| Category * | Citation of document, with indication, where appropriate, of the | relevant passages | | Relevant to claim No. |
| X | EP 0 780 127 A (PROCTER & GAMBL 25 June 1997 (1997-06-25) the whole document | Ε) | | 1-8 |
| A | & "Remington's pharmaceutical 14th edition" page 1557 -page 1560; table 6 | sciences | | 1-8 |
| X | WO 97 46243 A (PROCTER & GAMBLE 11 December 1997 (1997-12-11) |) | | 1-8 |
| A | page 2, line 18 - line 36 page 4, line 12 -page 5, line 19 page 7, line 32 -page 8, line 19 page 9 -page 10; examples 1-4 claims 1-3 & "Remington's pharmaceutical 14th edition" page 1557 -page 1560; table 6 | 3 | | 1-8 |
| | | -/ | | |
| = | er documents are listed in the continuation of box C. | X Patent lamily mem | bers are listed in | аппех. |
| A* documen conside | egories of cited documents: It defining the general state of the art which is not red to be of particular relevance | *T* later document published or priority date and not in cited to understand the invention | | |
| L' document which is | t which may throw doubts on priority claim(s) or cited to establish the publication date of another | "X" document of particular re cannot be considered no involve an inventive step | over or cannot be p when the docur | COnsidered to |
| Of document other ma | or other special reason (as specified) it referring to an oral disclosure, use, exhibition or eans | Y document of particular re cannot be considered to document is combined w | levance; the clair involve an inven | med invention live step when the |
| Hater tha | t published prior to the International filing date but n the priority date claimed | ments, such combination in the art. *&* document member of the | n being obvious t | o a person skilled |
| ale of the ac | tual completion of the international search | Date of mailing of the Inte | | |
| | December 2000 | 02/01/2001 | | |
| ane and ma | iling address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk | Authorized officer | | |
| | Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016 | Muller, S | | |

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Intern. sal Application No PCT/JP 00/05200

| Category • | Citation of document, with indication, where appropriate, of the relevant passages | |
|------------|--|-----------------------|
| | passages | Relevant to claim No. |
| P,X | WO 99 49984 A (PIETERS JULIAN ROBERT; WILKINSON ERIC (GB); LAWSON ROBERT ANDREW () 7 October 1999 (1999-10-07) page 2, line 8 -page 3, line 2 page 4, line 6 - line 12 page 5, line 1 -page 6, line 11 page 13 -page 14; example 3 | 1-8 |
| A | & "Remington's pharmaceutical sciences 14th edition" page 1557 -page 1560; table 6 | 1-8 |
| A | "Aldecin nasal spray" MEDICAL JOURNAL OF AUSTRALIA, vol. 2, no. 9, 1979, page 494 XP000971559 page 494, column 3 | 1-8 |
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Express Mail Label No.: EL395941438US

Information on patent family members

intern. .al Application No PCT/JP 00/05200

| Patent document Publication | | | | | |
|-----------------------------|---|------------------|---|--|--|
| cited in search repor | t | Publication date | Patent family member(s) | Publication date | |
| EP 0780127 | Α | 25-06-1997 | NONE | | |
| WO 9746243 | A | 11-12-1997 | AU 3153797 A BR 9709650 A EP 0954318 A JP 11511758 T | 05-01-1998 10-08-1999 10-11-1999 12-10-1999 | |
| WO 9949984 | Α | 07-10-1999 | AU 2741499 A | 18-10-1999 | |

Form PCT/ISA/210 (patent lamily annex) (July 1992)

Express Mail Label No.: EL395941438US



(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | FOR FURTHER see Notification of | of Transmittal of International Search Report |
|--|---|---|
| 00S0828P | ACTION (Form PCT/ISA/2 | (20) as well as, where applicable, item 5 below. |
| International application No. | International filing date (day/month/year) | (Earliest) Priority Date (day/month/year) |
| PCT/JP 00/05200 | 03/08/2000 | 07/08/1999 |
| Applicant | | |
| according to Analog 10. A copy is being that | prepared by this International Searching Auth nsmitted to the International Bureau. | ority and is transmitted to the applicant |
| This International Search Report consists of X It is also accompanied by a | of a total of4 sheets. a copy of each prior art document cited in this | report. |
| Basis of the report | | |
| With regard to the language, the ir language in which it was filed, unle | nternational search was carried out on the bas ss otherwise indicated under this item. | is of the international application in the |
| the international search wa Authority (Rule 23.1(b)). | s carried out on the basis of a translation of th | e international application furnished to this |
| contained in the internation filed together with the internation furnished subsequently to t furnished subsequently to t the statement that the subsinternational application as | al application in written form. national application in computer readable form his Authority in written form. his Authority in computer readble form. equently furnished written sequence listing do filed has been furnished. | |
| _ | d unsearchable (See Box I). | |
| 3. Unity of invention is lacking | ng (see Box II). | |
| 4. With regard to the title, | | |
| the text is approved as subr | | |
| the text has been establishe | ed by this Authority to read as follows: | |
| 5. With regard to the abstract, X the text is approved as submitthe text has been established within one month from the difference. | nitted by the applicant. d, according to Rule 38.2(b), by this Authority ate of mailing of this international search repo | as it appears in Box III. The applicant may, t, submit comments to this Authority. |
| 6. The figure of the drawings to be publish as suggested by the applica because the applicant failed because this figure better ch | ed with the abstract is Figure No. nt. to suggest a figure. | None of the figures. |

International Application No PCT/JP 00/05200

a. classification of subject matter IPC 7 A61K9/08 A61K A61K31/573 A61P37/08 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61K Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ, CHEM ABS Data C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Category ° Relevant to claim No. X EP 0 780 127 A (PROCTER & GAMBLE) 1-8 25 June 1997 (1997-06-25) the whole document Α "Remington's pharmaceutical sciences 1 - 814th edition" page 1557 -page 1560; table 6 χ WO 97 46243 A (PROCTER & GAMBLE) 1 - 811 December 1997 (1997-12-11) page 2, line 18 - line 36 page 4, line 12 -page 5, line 19 page 7, line 32 -page 8, line 18 page 9 -page 10; examples 1-4 claims 1-3 Α "Remington's pharmaceutical sciences 1-8 14th edition" page 1557 -page 1560; table 6 -/--Further documents are listed in the continuation of box C. Χ Patent family members are listed in annex. Special categories of cited documents: *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled *O* document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed *&* document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 18 December 2000 02/01/2001 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016 Muller, S

International Application No PCT/JP 00/05200

| C (Continu | ation) DOCUMENTS CONSIDERED TO BE RELEVANT | PCT/JP 0 | 0/05200 |
|------------|---|----------|-----------------------|
| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | | |
| | ntile relevant passages | | Relevant to claim No. |
| P, X | WO 99 49984 A (PIETERS JULIAN ROBERT; WILKINSON ERIC (GB); LAWSON ROBERT ANDREW () 7 October 1999 (1999-10-07) page 2, line 8 -page 3, line 2 page 4, line 6 - line 12 page 5, line 1 -page 6, line 11 page 13 -page 14; example 3 & "Remington's pharmaceutical sciences 14th edition" page 1557 -page 1560; table 6 | | 1-8 |
| A | "Aldecin nasal spray" MEDICAL JOURNAL OF AUSTRALIA, vol. 2, no. 9, 1979, page 494 XP000971559 page 494, column 3 | | 1-8 |
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Information on patent family members

International Application No PCT/JP 00/05200

| Patent document cited in search repor | t | Publication date | Patent family member(s) | Publication date |
|--|---|------------------|---|--|
| EP 0780127 | Α | 25-06-1997 | NONE | |
| WO 9746243 | Α | 11-12-1997 | AU 3153797 A BR 9709650 A EP 0954318 A JP 11511758 T | 05-01-1998 10-08-1999 10-11-1999 12-10-1999 |
| WO 9949984 | Α | 07-10-1999 | AU 2741499 A | 18-10-1999 |

PATENT COOPERAT TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
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in its capacity as elected Office

| Date of mailing (day/month/year) |
|----------------------------------|
| 02 May 2001 (02.05.01) |
| International 2012 12 At |

International application No. PCT/JP00/05200

International filing date (day/month/year) 03 August 2000 (03.08.00)

00S0828P

Priority date (day/month/year)

07 August 1999 (07.08.99)

Applicant's or agent's file reference

Applicant

AKUTSU, Rika et al

| 1. | The designated Office is hereby notified of its election made: |
|----|---|
| | X in the demand filed with the International Preliminary Examining Authority on: |
| | 18 January 2001 (18.01.01) |
| | in a notice effecting later election filed with the International Bureau on: |
| | |
| 2. | The election X was was not |
| | made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b). |
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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

R. Forax

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338.83.38